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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,999	12/29/2003	Rozalina Dimitrova	17638 (BOT)	8259

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,999	DIMITROVA ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,9,10 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9,10 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, & 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsia (US Patent No. 4736526). The Hsia reference discloses a guide 17 in figure 1 comprising a material having an upper face and a lower face, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which dermal area a botulinum toxin can be administered, and the material having a plurality of staggered perforations 19 which extend completely through the material from the upper face to the lower face, wherein the staggered perforations are spaced apart by a uniform distance provided by a plurality of contiguous geometric structures provided upon the material, wherein each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures, wherein the contiguous geometric structures are seen to be printed or etched upon the material, also the material is flexible, so that when the material is pressed against the dermal area, substantially all of the lower face of the material is in contact with the dermal area since the device is made of a clear plastic that would inherently be able to flex in order to contact portions of the dermal area, and

wherein the device is fully capable of being an injection guide for assisting administration of a botulinum toxin due to it's size, shape, and ability to work in the environment, also see the remarks to arguments listed below.

With respect to claims 7 & 9-10, wherein the material comprises a plurality of circles, seen as the borders of the perforations, and wherein they are deemed to be contiguous since the definition of contiguous is "very close or next to" and wherein the circles are deemed to be "very close" or "next to" each other, also wherein the perforations are located in the center of the circles since the border of the perforations outline the circle, also wherein the perforations are seen to be sized to permit the tip of a marker therethrough due to the size of the perforations of the reference and the varying sizes and shapes of markers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7, & 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson (US Patent No. 4580561) in view of Tener (US Patent No. 4427005). The Williamson reference discloses a guide in figures 1 & 3 comprising a material having an upper face and a lower face, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through

which dermal area a botulinum toxin can be administered, and the material having a plurality of staggered perforations 38 which extend completely through the material from the upper face to the lower face, wherein the staggered perforations are spaced apart by a uniform distance provided by a plurality of contiguous geometric structures provided upon the material, wherein the contiguous geometric structures are seen to be printed or etched upon the material, wherein each perforation of the plurality of staggered perforation is located within a geometric structure of the plurality of contiguous geometric structures, and wherein the device is fully capable of being an injection guide for assisting administration of a botulinum toxin due to it's size, shape, and ability to work in the environment. Now even though the Williamson reference does not disclose the guide to be made of a transparent material attention is directed to Tener. The Tener reference teaches the guides to be made of a transparent material, see col. 2 lines 33-42. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Williamson with the teachings of Tener in order to allow the user to see through the guide for seeing where injections/marks have been made. Also see the remarks to arguments listed below with respect to the amendments.

With respect to claims 3 & 5, wherein the material is deemed to be flexible since the degree of flexibility is not disclosed and claimed therefore if the material is capable of being flexed then the material is deemed flexible. Also, so when the material is pressed against the dermal area substantially all of the exterior border is in contact with

the dermal area since when the material is pressed against the skin a large portion of the border will be in contact with the dermal area.

With respect to claims 7 & 9-10, wherein the material comprises a plurality of circles, seen as the borders of the perforations, and wherein they are deemed to be contiguous since the definition of contiguous is "very close or next to" and wherein the circles are deemed to be "very close" or "next to" each other, also wherein the perforations are located in the center of the circles since the border of the perforations outline the circle, also wherein the perforations are seen to be sized to permit the tip of a marker therethrough due to the size of the perforations of the reference and the varying sizes and shapes of markers.

Claims 16, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson as applied to claims 1, 5, & 10. Now even though the references do not explicitly disclose the use of 40, 60, or 80 perforations it would be an obvious design choice to alter the amount of perforations in order to provide a larger or more precise guide for Williamson or to allow a larger range for Hsia.

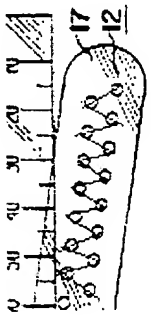
Claims 15, 17, & 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson. Now even though the references do not explicitly disclose the perforations to have a space of 1.5 or 2.0 cm between each other it would be an obvious design choice to do so in order to alter the range of the circles made with respect to Hsia and with location determination range with respect to Williamson, also

wherein it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a space of 1.5 or 2.0 cm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 12/28/06 have been fully considered but they are not persuasive.

Applicant argues that the staggered perforations are not spaced apart by a uniform distance, the examiner disagrees. The specification only describes a definition for the term "staggered" which the perforations of Hsia clearly are if a line is drawn through the circles and a right angle line is then drawn, the right angle line will not intersect a next row of perforations. Also wherein the uniform distance is seen as the distance between each perforation in the staggered pattern, a portion of the Hsia figure 1 is disclosed below with a line showing the staggered pattern and wherein there is a uniform distance between those perforations as shown by the zig-zag line that has been inputted.



The applicant is suggested to further clarify what is meant by the phrase "staggered perforations are spaced apart by a uniform distance" since under it's broadest reasonable interpretation the distance between the "staggered perforations" can clearly be seen above to be of a uniform distance. The same concept is utilized for the interpretation of the phrase with respect to Williamson.

The applicant argues that Williamson and Hsia do not disclose contiguous circles or that they are not drawn-printed or etched, the examiner disagrees. The contiguous circle is seen to be the outline of the circle and the perforation is seen to be all of the area within the circle. Since the applicant does not clarify that there is a space between the contiguous circle and the location of the perforation within the circle, the claims are clearly be interpreted that the contiguous circle can be the outline of the perforation or the perforation can be seen as all of the area within the outline of the contiguous circle. The structures can be seen to be etched or printed via the stamping or cutout process into the material due to the broad definitions of the terms of etching or printed. It is suggested to the applicant that the claims be amended to incorporate an area or space between the outline of the contiguous structures and the location of the perforation.

Applicant argues that Hsia does not disclose that the perforations are large enough to allow the tip of a marker therethrough, the examiner disagrees. The perforations of Hsia are clearly large enough to allow the tip of a marker therethrough. Also, wherein the size of the tips of markers vary and size and therefore the perforations of Hsia are fully capable of allowing the tip of a marker through.

Applicant argues that Williamson does not disclose the device to be flexible, the examiner disagrees. The definition is not fully disclosed of the term flexbile in the specification and therefore is open for interpretation. The only functional limitation stated for the amount of flexibility for Williamson is that "the material is flexible, so that when the material is pressed against the dermal area, substantially all of the lower face of the material is in contact with the dermal area". The material of Williamson could easily be placed against a patient's back or abdomen or thigh and substantially have all of the lower face be in contact with a dermal area. Therefore, the device of Williamson is seen to meet the limitation of the claim. Further amending to clarify the claims is suggested to the applicant but to keep in mind to not include new matter with respect to the flexibility of the device.

The applicant claims that Hsia or Williamson both fail to disclose that it would be obvious to have a larger number of perforations, the examiner disagrees. The applicant is directed to MPEP 2144.04 Section VI Part B: Duplication of Parts, wherein the courts have upheld in the case *In re Harza* wherein "the mere duplication of parts has no patentable significance unless a new and unexpected result is produced". Therefore, it would be obvious to duplicate the perforations in the device of Hsia or Williamson.

The applicant claims that Hsia or Williamson both fail to disclose that it would be obvious to have a larger space between the perforations, the examiner disagrees. The applicant is directed to MPEP 2144.04 Section IV Part A : Changes in Size/Proportion, wherein the courts have upheld the case *Gardern v.TEC systems, Inc.* wherein the "recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device". Therefore it would be obvious to one of ordinary skill in the art to change the spaces between the perforations as change in proportion.

The examiner would like to note that the applicant has been suggested to make amendments above with respect to the contiguous structures and the phrase "staggered perforations are spaced apart by a uniform distance".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons